CONTRACT CONCEPT REVIEW

NTP Board of Scientific Counselors Meeting
November 30 – December 1, 2010

Concept Title: **Sperm Count and Vaginal Cytology Evaluations**

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Purpose
The purpose of this contract is to provide for the evaluation of reproductive tissues obtained from 90-day toxicology studies conducted by the National Toxicology Program (NTP). The results of these evaluations are used by the NTP to help identify chemicals that have potential to be reproductive toxicants and, therefore, warrant further study in assays for reproductive toxicity.

Background and Concept Statement
Reproductive toxicity continues to be of major concern, both within the National Toxicology Program (NTP) and in the general public. The need to continue testing chemicals for possible reproductive toxicity in both sexes is greater than ever as evidenced by requests from other government agencies and academic scientists who recognize the unique resources of this Program.

The purpose of this contract is to perform Sperm Count and Vaginal Cytology Evaluations (SCVCE) on tissues obtained from animals in the NTP's 90-day toxicity studies. Activities performed under this contract will include: (1) evaluation of sperm counts through analysis of homogenization resistant testicular spermatid heads and (2) interpretation of vaginal cytology slides for evaluation of estrus cyclicity. Both of these endpoints are robust indicators of reproductive health. Tissues and slides for these analyses will be obtained from animals in toxicity studies of environmental agents conducted at various NTP-designated laboratories. The SCVCE Laboratory will provide reproductive expertise in evaluating of these specimens from the multiple laboratories.

Results from the SCVCE will provide a short-term "biomarker" for potential reproductive toxicity. Adverse findings from these evaluations will indicate that further study of reproductive effects is warranted.

The NTP has conducted more than 250 SCVCEs to date. The NTP continues to have interest in obtaining these and similar data to assess the quality of such results in predicting functional reproductive effects.

Proposed Changes to the Current Statement of Work
The work to be performed under this recompetition is the same as is currently being performed.